Frito-Lay, Inc.

August 13, 1999

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Dockets Management Branch
U.S. Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: **Update to the 1996 Study of Consumer Perception of the Olestra Information Label**

Reference: **Food Additives Permitted for Direct Addition to Food for Human Consumption: Olestra**
Docket No. 87F-0179; March 28, 1996

REVIEW OF THE 1996 STUDY:

In 1996, Frito-Lay, Inc. conducted a perception study to evaluate consumer understanding of the olestra information label and the resulting impact of the label on consumer perception of safety of products made with olestra. Part of that study was conducted using "before-and-after" type questions. Participants were shown informational statements about olestra (e.g., "Olestra is not absorbed or digested.") and then asked a series of questions about their perception of safety of products made with olestra. The participants then viewed the olestra information label and responded to the same questions about their perception of safety. The distribution of their answers was compared (before vs. after) using a Chi-squared statistical test. Also after viewing the label, participants were asked additional questions to determine how clearly they understood the statements. The 1996 study demonstrated that the label was viewed as a warning label rather than an information label. Only 16% of the participants concluded that olestra was safe to eat after viewing the olestra information label. The study also demonstrated that consumers did not understand the statements about vitamins and "other nutrients." Results of the 1996 study were submitted to FDA (Docket No. 87F-0179; March 28, 1996).

PURPOSE OF THE 1999 STUDY:

The 1996 perception study was conducted shortly after approval of olestra by the FDA but before availability of olestra in any product on the market and no participant had eaten a product made with olestra. That study showed the impact of the olestra information label on a "naive" population. Since the 1996 study, numerous significant events involving olestra have occurred including nationwide availability of the Frito-Lay WOW!™ Brand snackfoods made with olestra, the FDA Food Advisory Committee meeting (June 15-17, 1998), and many national and local news stories about olestra. Therefore, the 1999 study was done to determine whether the olestra information label was still capable of influencing consumer perception as in 1996.

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METHODS:

Perception testing was self-administered using the same protocol as the 1996 study (Docket No. 87F-0179; March 28, 1996). Participants (n = 233) were shown information about olestra (e.g., "Olestra is not digested or absorbed.") and then asked a series of questions about their perception of safety of products made with olestra. Participants then viewed the information label and were again asked about their perception of safety of products made with olestra. The distribution of their answers (before vs. after) was compared using a Chi-squared statistical test. Also after viewing the olestra information label, the participants were asked additional questions about the clarity of the statements on the label.

RESULTS:

Perception of Safety: **The olestra information label is perceived as a warning label.**

Study participants were shown the same background information as in the 1996 study and asked if they thought that a product made with olestra was safe, unsafe, or whether they were uncertain. Before seeing the information label, most (64%) were uncertain about safety, but only 15 participants (6%) thought that products made with olestra were unsafe. However, after viewing the label, a significant change ($p = 0.006$) in the distribution of responses occurred indicating a change in the perception of safety. Specifically, viewing the olestra information label caused the number of participants that believe that products made with olestra are unsafe to more than double (n = 37).

A symmetry test was conducted to evaluate migration of participants to different perception categories after reading the information label. The analysis demonstrated that the information label had the greatest impact on consumers that initially believed that products made with olestra were safe. Nineteen of the participants that initially believed olestra was safe migrated away from this perception after seeing the information label ($p = 0.002$). Of the participants that were initially uncertain about safety (n = 149), 21% (n = 32) migrated away from uncertainty after viewing the information label. Of those that shifted away from the "uncertain" group after seeing the label, a greater number migrated into the group believing that products made with olestra were unsafe (n = 20) than the number migrating into the "safe" group (n = 12). Importantly, not even one study participant from the group of participants that initially concluded that olestra was unsafe (n = 15) was influenced by seeing the label.

Clarity of the label: **Consumers do not understand the statement about gastrointestinal (GI) effects**

The olestra information label does not indicate the anticipated frequency of GI effects, only that they "may" occur. Numerous published double-blind, placebo-controlled studies have demonstrated that the incidence of GI effects in consumers eating snackfoods made with olestra is no greater than in consumers eating products made with vegetable oil. Most recently in the study by Sandler and co-workers involving more than 3,000 participants[1]. The incidence of GI effects was uncommon regardless of the oil in which the snackfoods were cooked.

In this study, more than 1 in 4 consumers believed that GI effects would occur 20-50% of the time they ate products made with olestra after reading the information label. As suggested by several members of the FDA Food Advisory Committee Meeting in 1998, the majority of participants (58%) stated that they would delay seeking medical attention if GI changes occurred after eating a product with the olestra information label. The concern being that consumers could experience non-olestra related GI effects, potentially severe in nature, for which they should seek medical attention but would not do so because they would incorrectly attribute the effects to olestra.

Clarity of the label: **Consumers do not understanding the statement about vitamins and other nutrients**

Olestra oil can inhibit the absorption of lipophilic vitamins. For that reason, the FDA Final Rule for olestra required addition of compensatory concentrations of vitamins A, D, E, and K to all products made with olestra to prevent net loss. Addition of the compensatory vitamins is indicated in the final statement in the information label ("Vitamins A, D, E, and K have been added."). However, after reading the information label, only 24% of the study participants concluded that products made with olestra do not affect the levels of these vitamins in the body. The information label clearly states that olestra can affect the absorption of other nutrients. Surprisingly, even with the direct statement concerning the influence of olestra on the absorption of "other nutrients," an approximately equal distribution of participants concluded that olestra did (53%) or did not (47%) affect the absorption of "other nutrients."

Clarity of the label: **Consumers believe they do understand the statements in the label**

Despite the results demonstrating that the participants did not understand the intended messages in the information label, the overwhelming majority still thought that it was at least moderately clear (93% in 1996 and 95% in 1999).

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[1] Sandler RS, Zorich NL, Filloon TG, Wiseman HB, Lietz DJ, Brock MH, Royer MG, and Miday RK. 1999. Gastrointestinal symptoms in 3181 volunteers ingesting snack foods containing olestra or triglycerides. A 6-week randomized, placebo-controlled trial. Ann Intern Med 16;130(4 Pt 1):253-61.

CONCLUSIONS:

The present study demonstrates that the ability of the olestra information label to influence consumer perception has not changed substantially since 1996 and that it clearly does not serve the purpose for which it was intended. Consumers do not understand the individual statements on the olestra information label and they conclude that it is a warning label. This is particularly disturbing in light of the fact that such a great proportion of the participants believed that the label was at least moderately understandable. While perception of understanding is subjective, the fact that the overwhelming majority of participants believed they understood the label, accompanied by the background demonstrating that they clearly do not, is a powerful statement that the information label is ineffective.

RECOMMENDATIONS:

Because controlled clinical studies have shown no meaningful GI effects in people that eat snackfoods made with olestra, the statement about potential for GI changes should be removed. Additionally, the results from this study suggest that consumers are likely to incorrectly attribute GI changes to olestra when they should seek medical attention. As recommended by the majority of the Food Advisory Committee (FAC) in it's 1998 meeting, we support removing the statement about inclusion of compensatory concentrations of lipophilic vitamins and asterisking their presence in the ingredient statement ("* Not a nutritional source of these vitamins.").

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